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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------|------------------|
| 09/919,360 | 07/30/2001 | Leroy E. Hood | P-IS 4627 | 2535 |
| 23601 | 7590 | 02/24/2004 | | |
| CAMPBELL & FLORES LLP 4370 LA JOLLA VILLAGE DRIVE 7TH FLOOR SAN DIEGO, CA 92122 | | | EXAMINER MARSCHEL, ARDIN H | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

G.A.M.

Office Action Summary**Application No.**

09/919,360

Applicant(s)

HOOD ET AL.

Examiner

Ardin Marschel

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 17-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-16, and 30-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. <u>(4/2/04)</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election with traverse of Group I (Specie A: Beneficial drug reaction such as the alleviation of a sign or symptom associated with a condition as in instant claim 4), (claims 1, 2, 4-16, and 30-43), in the Paper, filed 11/24/03, is acknowledged. The traversal is on the ground(s) that a search for the distinct subject matter of Group I will "likely" and thus "of necessity" reveal the distinct subject matter of Group II. This is not found persuasive because applicants have admitted the distinctness of the subject matter between Groups I and II and also have not argued why the undue search burden supported by this distinctness as set forth in the previous office action, mailed 9/22/03, still does not define a separate and undue search burden to search Groups I and II together. It is also noted that even within a particular document that distinct subject matter would require a separate additional search over the inventions of Groups I vs. Group II. It is noted that no traversal argument has been submitted regarding the specie election requirement and that claim 3 is withdrawn as being directed to a non-elected specie.

The requirement is still deemed proper and is therefore made FINAL.

PRIOR ART

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-16, and 30-43 are rejected under 35 U.S.C. 102(a) and

(e)(2) as being clearly anticipated by Friend et al. (P/N 6,218,122).

In the title and abstract Friend et al. summarizes the monitoring of cellular constituents in connection with therapies. The drug therapy practice perturbs the systems of an individual and thus perturbation response profiles are produced in the disclosure of Friend et al. Figures 1 – 3 depict various multidimensional coordinate point response profiles as in the instant claim limitations. The DETAILED DESCRIPTION section of the reference in column 4, line 46, through column 29, line 39, go on at length and in detail for such response profile production and analysis. This is also the subject matter of the instant claims with a specific classification of a group of individuals into a drug response population regarding disease states being treated. See, for example, column 6, line 48, through column 8, line 62. Cellular constituents being measured for such profiles include RNA and protein expression as set forth, for example, in column 2, lines 38-47, as also required in instant claims 11-13. The elected specie of the beneficial drug response for alleviating a sign or symptom associated with a disease as in instant claim 4 is also set forth in the reference in column 8, lines 35-39. The basic classification of a population by drug responsiveness as instantly claimed is set forth in the reference in column 9. lines 2-14 and lines 39-47, as monitoring subjects as to efficacy of a drug therapy in a clinical trial.

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Various molecules may be monitored regarding expression profiles, such as small molecules (instant claim 15) like glucose as set forth in the reference in column 12, lines 34-41, or antibodies (instant claim 14) as in the reference in column 12, lines 62-65. An array as a target for cellular measurements is disclosed in column 20, lines 55-59, as in instant claim 10. Leukocyte specimen measurements (as in instant claim 16) are disclosed in the reference via the white blood cell profiling set forth in column 12, lines 31-41.

No claim is allowed.


Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571)272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571)272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571)272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 20, 2004


ARDIN H. MARSCHEL
PRIMARY EXAMINER